

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

ENDO PHARMACEUTICALS INC.,

Plaintiff,

v.

ROXANE LABORATORIES, INC.,

Defendant.

Case No. 13-cv-3288-TPG

**ECF FILED VERSION
REDACTED**

**MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFF'S MOTION TO STRIKE
ROXANE'S AFFIRMATIVE DEFENSE OF UNCLEAN HANDS**

TABLE OF CONTENTS

INTRODUCTION	1
FACTUAL BACKGROUND	2
Background of prior litigation	2
Endo’s Improper Interference with Roxane’s Commercial Relationship	3
.....	
.....	6
Endo filed a false declaration in this Court in an attempt to obtain equitable relief.....	8
Endo refused to produce a full and unredacted copy of the PPA knowing that it contained a grant back license	10
Endo used its acquisition of the ‘482 patent to procure rights to another patent--owned by Mallinckrodt—that it has now asserted in a new action against Roxane filed in Delaware	11
Endo had Notice of Roxane’s Unclean-Hands Defense for Nearly Nine Months.....	13
ARGUMENT	13
I. Endo’s motion is procedurally improper.	14
II. Endo comes to this Court with unclean hands.	15
III. Roxane’s unclean-hands defense is not a surprise to Endo.	18
IV. Unclean hands is not a guise to reassert Roxane’s license defenses.....	19
CONCLUSION.....	19

TABLE OF AUTHORITIES

	Page(s)
CASES	
<i>eBay Inc. v. MercExchange, L.L.C.</i> , 547 U.S. 388 (2006).....	17
<i>EEOC v. Kelley Drye & Warren, LLP</i> , No. 10 Civ. 655(LTS), 2011 U.S. Dist. LEXIS 80673 (S.D.N.Y. July 25, 2011).....	14
<i>Endo Pharm. Inc. v. Actavis, Inc.</i> , 746 F.3d 1371 (Fed. Cir. 2014).....	10
<i>Endo Pharmaceuticals Inc. v. Roxane Laboratories, Inc.</i> , Case No. 14-cv-1387-RGA (D. Del.) D.I. 1	11
<i>Endo Pharms., Inc. v. Mylan Pharms., Inc.</i> , 2014 U.S. Dist. LEXIS 76251 (D. Del. Apr. 8, 2014), <i>aff'd</i> , 2014 U.S. App. LEXIS 23249 (Fed. Cir. Dec. 4, 2014.)	10
<i>Estee Lauder, Inc. v. Fragrance Counter, Inc.</i> , 189 F.R.D. 269 (S.D.N.Y. 1999)	13
<i>France Telecom S.A. v. Novell, Inc.</i> , No. 102-437-GMS, 2002 WL 31355255 (D. Del. Oct. 17, 2002).....	15
<i>Gaudiosi v. Mellon</i> , 269 F.2d 873 (3d Cir. 1959).....	17
<i>Keystone Driller Co. v. Gen. Excavator Co.</i> , 290 U.S. 240 (1933).....	15, 16, 18
<i>Koch v. Pechota</i> , 2013 U.S. Dist. LEXIS 106472 (S.D.N.Y. 2013).....	13
<i>Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.</i> , 324 U.S. 806 (1945).....	15
<i>Raymond Weil, S.A. v. Theron</i> , 585 F. Supp. 2d 473 (S.D.N.Y. 2008).....	13
<i>RSM Prod. Corp. v. Friedman</i> , 643 F. Supp. 2d 382 (S.D.N.Y. 2009).....	13
<i>Salcer v. Envicon Equities Corp.</i> , 744 F.2d 935, 939 (2d Cir. 1984), 471 U.S. 1098 (1986).....	13

<i>Walsh v. City of New York</i> , 585 F. Supp. 2d 555 (S.D.N.Y. 2008).....	13
--	----

OTHER AUTHORITIES

Fed. R. Civ. P. 12(f).....	14, 18
Fed. R. Civ. P. 30(b)(6).....	11
U.S. Patent No. 5,662,933.....	3
U.S. Patent No. 5,958,456.....	3
U.S. Patent No. 7,276,250.....	3
U.S. Patent No. 7,851,482.....	passim
U.S. Patent Nos. 8,808,737	11

INTRODUCTION

Endo's baseless motion is just part and parcel of its wrongful multi-year multi-faceted scheme to keep Roxane from bringing its generic extended release oxymorphone product to the market. Endo filed this lawsuit seeking the relief of an injunction, an equitable remedy. But Endo's actions both before this action was filed and while this case has been pending should close the courthouse door to equitable relief. These actions include:

- improperly interfering with Roxane's contractual rights under Roxane's oxymorphone supply agreement with Johnson Matthey by [REDACTED]
[REDACTED]
[REDACTED]
- [REDACTED]
[REDACTED]
- filing a baseless citizen petition with FDA to try to get the agency to determine that Endo discontinued its original formulation Opana® ER for safety reasons when the true goal was to squelch generic competition as part of a product-hopping strategy;
- asserting a patent against Roxane knowing that Roxane already had license rights under that patent from Johnson Matthey;
- falsely stating to Roxane that Johnson Matthey would not let Endo produce a full and unredacted copy of an agreement (the "patent purchase agreement" or "PPA") memorializing [REDACTED]
- presenting a false declaration to this Court in pursuit of an equitable remedy against Roxane, and;

- procuring and asserting additional patent rights against Roxane in Delaware that Endo would not have been able to obtain without improperly interfering with Roxane’s contractual rights.

Endo must learn that the end it seeks here, an injunction, does not justify the wrongful means it has employed.

Endo’s motion to strike is untimely, coming long after it has responded to Roxane’s amended answer containing its unclean-hands defense, and long after Endo itself *consented* to Roxane amending its answer to assert this defense. The Court should deny the motion for this reason alone.

That said, both of the premises behind Endo’s motion to strike are easily proven wrong. Contrary to Endo’s representation, unclean hands is not a new defense: Endo itself agreed in June 2014 to allow Roxane to amend its answer to add this very defense. And, unclean hands is not a license defense: it is an equitable—not a legal—defense that is based on a wide variety of misdeeds, summarized above, and far more than just the license negotiations.

To fully understand the issues here, it is necessary to review Endo’s conduct in context, which we now spell out in detail.

FACTUAL BACKGROUND

Background of prior litigation

In November 2009, Roxane filed its Abbreviated New Drug Application (“ANDA”) seeking FDA approval to manufacture and sell a generic alternative to Endo’s original formulation of Opana® ER. At that time, Endo had three patents listed in FDA’s Orange Book^{*}

^{*} The Orange Book is an FDA publication where brand companies list all patents purportedly covering a given drug.

as covering Endo’s original formulation of Opana® ER: the ‘933 patent, ‘456 patent, and ‘250 patent[†]—none of which are currently involved in this action.

In early 2010, Endo sued Roxane alleging infringement of the ‘456 patent and covenanted not to sue Roxane over the other two Orange Book-listed patents related to original Opana® ER. The 2010 litigation settled and Roxane and Endo entered into a settlement and license agreement under which [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Once the 2010 litigation was settled, however, Endo adopted a product-hopping strategy that involved erecting roadblocks to prevent Roxane from entering the market while Endo abandoned its original formulation Opana® ER and turned its attention to an allegedly tamper-resistant formulation.

Endo’s Improper Interference with Roxane’s Commercial Relationship

At the time Roxane settled the 2010 litigation, Roxane had Johnson Matthey lined up as its supplier of active pharmaceutical ingredient (“API”) oxymorphone hydrochloride to be used in Roxane’s ANDA product. (Ex. 2; *see also* Ex. 3.) [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[†] U.S. Patent No. 5,958,456 (“‘456 patent”), U.S. Patent No. 5,662,933 (“‘933 patent”), and U.S. Patent No. 7,276,250 (“‘250 patent”).

In 2012, Endo and Johnson Matthey engaged in discussions relating to Endo's potential purchase of the '482 patent[‡] from Johnson Matthey. During those discussions, Johnson Matthey concluded [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

In a second internal Johnson Matthey email, Johnson Matthey expanded on that theme,

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[‡] U.S. Patent No. 7,851,482 ("482 patent")

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

As mentioned above, during the 2011 settlement discussions, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

When FDA refused to grant Endo's citizen's petition, Endo sued the agency seeking to require it to agree that the old formulation was discontinued for safety reasons and to force the agency to immediately withdraw the approvals of generic versions of non-tamper-resistant formulations of extended-release oxymorphone hydrochloride. (Ex. 13; s [REDACTED] [REDACTED].) Endo's lawsuit also sought to require FDA to suspend the approval of any ANDAs for any non-tamper-resistant versions currently under review. (Ex. 13; [REDACTED] [REDACTED])

Endo lost its suit against FDA, with the court disagreeing with Endo that Endo had withdrawn for safety reasons the original Opana® ER formulation that Roxane and others were seeking to market. (Ex. 14.)

Second, on May 15, 2013, Endo initiated the present lawsuit by suing Roxane on three additional patents: the '482 patent, '122 patent, and '216 patent, claiming that Roxane's ANDA infringed those patents. (D.I. 1 at ¶ 18-23.)

Endo filed a false declaration in this Court in an attempt to obtain equitable relief

After Endo lost its suit against FDA, and once Roxane and other generic companies received FDA approval to market the original Opana® ER formulation, Endo moved this Court, in August of 2013, to enjoin Roxane bringing its generic version of original formulation Opana® ER to market. (D.I 30.) In a reply brief submitted in support of its motion for preliminary injunction motion Endo filed the declaration of Guy Donatiello. (Ex. 16). In paragraph 39 of his declaration, Donatiello stated:

[REDACTED]

[REDACTED]

[REDACTED]

Endo submitted Donatiello's declaration two days before the preliminary-injunction hearing. [REDACTED] Roxane did not have any opportunity to cross-examine Donatiello as to any of the statements in his declaration.

During discovery, however, Roxane took Donatiello's deposition and questioned him as to the statements made in paragraph 39 of his declaration:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

This is not the first time Donatiello's credibility has been called into question over statements made in the settlement of a pharmaceutical patent case. *See Endo Pharms., Inc. v. Mylan Pharms., Inc.*, 2014 U.S. Dist. LEXIS 76251 (D. Del. Apr. 8, 2014) (finding "disconcerting" Donatiello's inconsistent positions regarding whether a settlement was consummated), *aff'd*, 2014 U.S. App. LEXIS 23249 (Fed. Cir. Dec. 4, 2014.)

[REDACTED]

[REDACTED] And in reversing, the Federal Circuit relied on Donatiello's declaration (which had not been subject to cross-examination) in holding that Endo's 2011 license to Roxane did not expressly cover the patents asserted in this lawsuit. *See Endo Pharm. Inc. v. Actavis, Inc.*, 746 F.3d 1371, 1375 (Fed. Cir. 2014) (noting evidence of license negotiations).

Endo refused to produce a full and unredacted copy of the PPA knowing that it contained a grant back license [REDACTED]

Endo's improper behavior has carried over to its conduct in this litigation. Since the outset of this lawsuit, Roxane attempted to obtain a full and unredacted version of the PPA because it suspected that there was crucial information and evidence of improper conduct hidden within those redacted sections. (Ex. 16.) [REDACTED]

[REDACTED]

[REDACTED] Not surprisingly, [REDACTED], Endo refused to produce the full and unredacted copy of the PPA and represented to Roxane that

Johnson Matthey had instructed Endo not to provide Roxane with a full and unredacted copy of the PPA. (Ex. 16.) Roxane was therefore required to subpoena the full and unredacted copy directly from third-party Johnson Matthey and engage in months-long third-party discovery motion practice to obtain that full document. (*Id.*; *see also* D.I. 37- 39, D.I. 41-42, D.I. 47, D.I. 48, D.I. 51, D.I. 88, D.I. 95, and D.I. 97-98)

During the deposition of Johnson Matthey’s Fed. R. Civ. P. 30(b)(6) witness that Roxane was finally able to take on February 11, 2015, Roxane learned from that witness, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Endo used its acquisition of the ‘482 patent to procure rights to another patent--owned by Mallinckrodt—that it has now asserted in a new action against Roxane filed in Delaware

Endo’s improper behavior extends even beyond this litigation. On November 7, 2014, Endo filed a third lawsuit against Roxane, this one in the District of Delaware alleging infringement of: U.S. Patent Nos. 8,808,737 (“the ‘737 patent”); and 8,871,779 (“the ‘779 patent”) seeking to enjoin Roxane from selling Roxane’s same extended-release oxymorphone ANDA product at issue in this lawsuit. (Ex. 18, *Endo Pharmaceuticals Inc. v. Roxane Laboratories, Inc.*, Case No. 14-cv-1387-RGA (D. Del.) (D.I. 1).)

Endo acquired rights in the ‘779 patent, which Endo is asserting in Delaware, as part of a settlement agreement between Endo and another company, Mallinckrodt. (*See* Exs. 19, 20, 21.) In that settlement, Endo used the ‘482 patent as a bargaining chip to obtain those rights. (Endo and Mallinckrodt were involved in an interference proceeding to determine priority of invention

between the ‘482 patent and Mallinckrodt’s patent application that issued as the ‘779 patent. That interference was resolved by settlement with Endo taking an adverse judgment.) (*See* Exs. 20, 21.) As a result of the interference and a subsequent *Inter Partes Review* proceeding that Amneal filed challenging the validity of the ‘482 patent, Endo canceled all four asserted claims of the ‘482 patent. (Ex. 22.) Endo has now requested that the Court enter an adverse judgment against it in this litigation with respect to the ‘482 patent. (Ex. 23.) But Endo did not make that request until after it had used the ‘482 patent as leverage to gain exclusive license rights to the ‘779 patent from Mallinckrodt and asserted the ‘779 patent in another litigation in another jurisdiction. (Ex. 21.)

So in addition to a product-hopping strategy, Endo has engaged in a *patent-hopping* strategy to the detriment of all of the companies seeking to enter the market with a generic extended-release oxymorphone hydrochloride product. (*See* Exs. 20, 21) Endo would not have been in a position to participate in a settlement of the interference proceeding, involving the ‘482 patent and the ‘779 patent, to gain rights in the ‘779 patent, had it not purchased the ‘482 patent from Johnson Matthey. (*Id.*) Thus Endo continues to profit from its original interference with Roxane’s contractual rights under the Johnson Matthey supply agreement and the results reverberate to this day.

Moreover, the presence of that Delaware action, with the ‘779 patent at issue, guarantees that this Court will not have the final word even after the time and expense of a trial. Once this case concludes, Roxane and the other defendants will have to contend with yet another Opana® ER lawsuit seeking to enjoin the same generic products from market entry. (D.I. 1, at Page 12, Section G.)

Endo had Notice of Roxane's Unclean-Hands Defense for Nearly Nine Months

On May 30, 2014, counsel for Roxane contacted Endo to advise that Roxane intended to seek leave of Court to file an amended answer and counterclaims to assert the affirmative defenses of implied license, express license, and unclean hands, providing Endo with a draft of its proposed answer and counterclaims. (Ex. 24.) Following a meet and confer held on June 6, 2014, counsel for Endo advised Roxane that although it opposed the amendment with respect to the license defenses, it “does not oppose amendment with respect to the proposed Twelfth Affirmative Defense (Unclean Hands).” (Ex. 25, June 6, 2014 email C. Gismervig to W. Bleibel.)

Roxane filed its motion for leave to file its amended answer with this Court on July 23, 2014. (D.I. 65.) Endo answered that motion, again not opposing the additional affirmative defense of unclean hands. (D.I. 71.) The Court granted Roxane leave to amend its answer to include the additional affirmative defense of unclean hands. (D.I. 99.) Roxane filed with the Court its amended answer (D.I. 101) and Endo responded to that pleading on December 8, 2014. (D.I. 102.)

ARGUMENT

Motions to strike are viewed with disfavor and infrequently granted. *Walsh v. City of New York*, 585 F. Supp. 2d 555, 557 (S.D.N.Y. 2008)); *see also Estee Lauder, Inc. v. Fragrance Counter, Inc.*, 189 F.R.D. 269, 272 (S.D.N.Y. 1999); *RSM Prod. Corp. v. Friedman*, 643 F. Supp. 2d 382, 394 (S.D.N.Y. 2009); *Koch v. Pechota*, 2013 U.S. Dist. LEXIS 106472 (S.D.N.Y. 2013); *see also Raymond Weil, S.A. v. Theron*, 585 F. Supp. 2d 473, 489-490 (S.D.N.Y. 2008) (noting that motions to strike affirmative defenses wasted not only the client's money but also

the court's time). Allegations may not be stricken simply because the movant challenges their factual basis. *Brokke v. Stauffer Chem. Co.*, 703 F. Supp. 215, 223 (D. Conn. 1988).

A motion to strike an affirmative defense for legal insufficiency should not be granted “unless it appears *to a certainty* that plaintiff would succeed despite any state of the facts which could be proved in support of the defense.” *Salcer v. Envicon Equities Corp.*, 744 F.2d 935, 939 (2d Cir. 1984) (*vacated on other grounds*, 471 U.S. 1098 (1986)) (citing *Durham Industries, Inc. v. North River Insurance Co.*, 482 F. Supp. 910, 913 (S.D.N.Y. 1979) (emphasis added); *see also Walsh v. City of New York*, 585 F. Supp. 2d 555, 557 (S.D.N.Y. 2008) (holding that the moving party bears the burden of demonstrating “to a certainty that [she] would succeed”). “It must be shown that the allegations being challenged are so unrelated to plaintiff’s claims as to be unworthy of any consideration as a defense and that their presence in the pleading throughout the proceeding will be prejudicial to the moving party.” 5C Charles Alan Wright & Arthur R. Miller, FEDERAL PRACTICE AND PROCEDURE § 1380 at 397 (3d ed. 1990).

In reviewing Endo’s motion to strike, “the Court views the pleading under attack most favorably to the pleader.” *EEOC v. Kelley Drye & Warren, LLP*, No. 10 Civ. 655(LTS), 2011 U.S. Dist. LEXIS 80673 (S.D.N.Y. July 25, 2011) (*quoting Wohl v. Blair & Co.*, 50 F.R.D. 89,91 (S.D.N.Y. 1970).

A party is not free to make a motion to strike at any time. A motion to strike must be brought “by a party either before responding to the pleading or if a response is not allowed, within 21 days after being served with the pleading.” Fed. R. Civ. P. 12(f).

I. Endo’s motion is procedurally improper.

Endo’s motion is untimely. It is brought under Rule 12(f), but the Rule provides, in a portion that Endo’s brief conveniently omits, that motions to strike an affirmative defense must be brought before responding to the pleading, or if no response is allowed, within 21 days after

being served. Here, Roxane duly amended its answer to assert unclean hands as a defense, and Endo responded to the pleading. (D.I. 101; D.I. 102.) Now, nine months later, Endo seeks to strike the very defense that it consented to Roxane asserting in an amended answer. It is too late. *See, e.g., Action Nissan, Inc. v. Hyundai Motor Amer.*, 617 F. Supp. 2d 1177, 1186-87 (M.D. Fla. 2008) (denying motion to strike as untimely under Rule 12(f)); *Cowart v. City of Eau Claire*, 571 F. Supp. 2d 1005, 1008 (W.D. Wis. 2008) (same).

Further, Endo's motion raises some of the same issues it argued at the March 6 status hearing. At that hearing, Endo's counsel repeatedly tried to have this Court remove Roxane's unclean-hands defense from the case. (Ex. 26, at 5:20-13:21.) The Court appropriately declined to foreclose Roxane from bringing this defense at trial.

II. Endo comes to this Court with unclean hands.

Roxane's unclean-hands defense is meritorious. Endo comes before this Court in equity, seeking to enjoin Roxane from bringing to market an extended-release version of Opana® ER. To be successful, however, Endo must act fairly and equitably both before and during the pendency of the litigation. Endo has not. Therefore, the equitable relief that Endo seeks against Roxane should be denied, for "he who comes into equity must come with clean hands." *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945).

As the Supreme Court has recognized, unclean hands is a "self-imposed ordinance that closes the doors of a court of equity to one tainted with inequity or bad faith relative to the matter in which he seeks relief...." *Id.* Unclean hands "is one of the fundamental principles upon which equity jurisprudence is founded." *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 244 (1933) The doctrine of unclean hands has no formulaic approach nor does it seek to put limits on this court's "free and just exercise of discretion" when evaluating whether the party seeking relief is guilty of misconduct. *Precision Instrument Mfg.*, 324 U.S. at 815.. (citing

Keystone Driller Co. v. Gen. Excavator Co., 290 U.S. 240, 245-46 (1933)); *see also France Telecom S.A. v. Novell, Inc.*, No. 102-437-GMS, 2002 WL 31355255, at *3-4 (D. Del. Oct. 17, 2002) (“Unclean hands...remains a broad defense less amenable to a particular checklist of elements.”) “Any willful act concerning the cause of action which rightfully can be said to transgress equitable standards of conduct is sufficient cause for the invocation of the maxim” by this court. *Precision Instrument Mfg. Co.* 324 U.S. at 815.

The Supreme Court’s decision in *Keystone Driller* illustrates the proper application of unclean hands. *Keystone* involved the plaintiff’s procurement of a false affidavit to cover up evidence of a prior use that called into question the validity of only one of the patents in suit. Yet the *Keystone* Court held that such conduct was sufficient to bar the patentee from any recovery in the lawsuit on any of the five patents in suit. *Keystone*, 290 U.S. at 244-45.

The *Keystone* Court reasoned that before a complainant can have a standing in court he must first show that not only has he a good and meritorious cause of action, but he must come into court with clean hands.” *Id.* at 244. “He must be frank and fair with the court, nothing about the case under consideration should be guarded, but everything that tends to a full and fair determination of the matters in controversy should be placed before the court.” *Id.*

Here, Endo’s actions should foreclose the equitable remedy it seeks against Roxane. Endo has not been “frank and fair” with either Roxane or the Court. Endo engaged in a series of misdeeds before it filed this lawsuit, during its pendency, and its misdeeds have even extended to other litigation in Delaware.

That improper conduct, spelled out in detail above, includes: 1) [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]; 2) [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] 3) filing a citizen petition requesting FDA to determine that its original non-crush-resistant version of Opana® ER was discontinued for safety reasons and could no longer serve as a reference listed drug for an ANDA application; 4) asserting the ‘482 patent against Roxane when it knew that Roxane already had licensed rights under that patent from Johnson Matthey; 5) falsely stating to Roxane that Johnson Matthey demanded that only a redacted version of the PPA be produced and forcing Roxane to expend considerable resources to subpoena and engage in lengthy third-party motion practice with Johnson Matthey to obtain an unredacted copy of the PPA; 6) presenting a false declaration to this Court in pursuit of an equitable remedy against Roxane; and 7) procuring and asserting additional patent rights against Roxane in Delaware that Endo would not have been able to gain without improperly interfering with Roxane’s contractual rights through the purchase of the ‘482 patent.

The requirement of clean hands “gives wide sweep to the equity court’s exercise of discretion ‘in refusing to aid the unclean litigant.’” *Gaudiosi v. Mellon*, 269 F.2d 873, 881 (3d Cir. 1959) (citing *Precision Instrument*, 324 U.S. at 815). “Public policy not only makes it obligatory for courts to deny a plaintiff relief once his ‘unclean hands’ are established but to refuse to even hear a case under such circumstances.” *Id.* at 882. Since Endo does not come to this Court with clean hands, it is not entitled to the equitable relief it seeks. *See eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 394 (2006) (“We hold ... that the decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts, and that

such discretion must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards.”). The motion to strike should be denied.

III. Roxane’s unclean-hands defense is not a surprise to Endo.

Contrary to its representation, Endo was not surprised by Roxane’s unclean-hands defense. Since Endo is the primary actor, it has known all along of the facts giving rise to this defense and the possibility that those facts might come to light. When Roxane learned of just a few of those facts, it promptly advised Endo in May 2014 that it would be seeking to amend its answer to include an unclean-hands defense—consenting to the unclean-hands defense—of which Endo consented. Endo did not object, and after Roxane filed its amended answer Endo responded to the pleading.

Furthermore, when Endo approached Roxane requesting a stipulation to dismissal of the ‘482 patent in November 2014, Roxane reiterated its intention to preserve its right to assert an unclean-hands defense: “Roxane’s defense of unclean hands shall survive the entry of this partial final judgment and Roxane shall be allowed to pursue all the equitable relief against Endo available to Roxane to the extent permitted by *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240 (1933) and its progeny.” (Ex. 23.)

Thus, Endo had no basis to complain at the January 23, 2015 hearing, about the unclean-hands defense: “First we have heard of it”; and “I don’t actually think it is in the case at this point.” (Ex. 27 at 124:16, 124:21-23.) These representations to the Court cannot be reconciled with Endo’s earlier decision not to oppose Roxane’s request to amend its answer to assert this very defense.

IV. Unclean hands is not a guise to reassert Roxane's license defenses

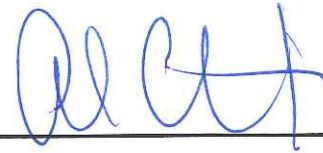
Nor is the unclean-hands defense a “guise” for Roxane to reassert its license defenses. As explained in detail above, Roxane's unclean-hands defense is based on a wide range of improper conduct on Endo's part, not just the false declaration Endo submitted in conjunction with the preliminary injunction proceedings. Moreover, unclean hands is an entirely separate equitable defense with entirely different elements than the legal defense of a license. And, unclean hands is a broader defense that precludes the plaintiff from obtaining the equitable relief that it seeks. (Ex. 28.)

CONCLUSION

For the above reasons, the Court should deny Endo's Rule 12(f) motion to strike Roxane's unclean-hands defense.

Dated: March 12, 2015

By:



Alan B. Clement
Paul Sudentas
Locke Lord LLP
3 World Financial Center
New York, New York 10281
(212) 415-8600

OF COUNSEL

Keith D. Parr
Scott B. Feder
Myoka Kim Goodin
Amanda K. Kelly
Wasim K. Bleibel
Locke Lord LLP
111 S. Wacker Drive
Chicago, IL 60606
(312) 443-0700

*Attorneys for Defendant
Roxane Laboratories, Inc.*

CERTIFICATE OF SERVICE

I hereby certify that on this 12th day of March, 2015, I served the foregoing MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFF'S MOTION TO STRIKE ROXANE'S AFFIRMATIVE DEFENSE OF UNCLEAN HANDS and declaration with exhibits in support thereof, by causing a copy of the same to be delivered via email to:

Martin J. Black
DECHERT LLP
Cira Centre
2929 Arch Street
Philadelphia, PA 19104

martin.black@dechert.com

Jonathon Loeb
DECHERT LLP
2440 W. El Camino Real, Suite 700
Mountain View, CA 94040

jonathan.loeb@dechert.com

Robert D. Rhoad
DECHERT LLP
902 Carnegie Center
Suite 500
Princeton, NJ 08540

robert.rhoad@dechert.com



Wasim K Bleibel